Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Departmental Appeals Board, MS 6127
Medicare Appeals Council
330 Independence Avenue
Cohen Building, Room G-644
Washington, DC 20201
(202)565-0100/Toll Free:1-866-365-8204

MAY 18 2018

ALJ Appeal Number: 1-5903036090
Docket Number: M-18-1749 (formerly Docket No. M-17-7640)

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NOTICE OF ACTION OF MEDICARE APPEALS COUNCIL
DENYING REQUEST TO REOPEN

What This Notice Means

Enclosed is a copy of an order by the Medicare Appeals Council denying your request to reopen in the subject case. If you have any questions, you may contact the Centers for Medicare & Medicaid Services regional office or the local Medicare contractor.

Enclosure

cc: Jonathan Bloom
Minimed Distribution Corp.
Q2A AdQIC Records Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ACTION OF MEDICARE APPEALS COUNCIL
DENYING REQUEST FOR REOPENING
Docket Number: M-18-1749
(formerly Docket No. M-17-7640)

In the case of	**Claim for**
J.B. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
Jonathan Bloom (Beneficiary)	XXX-XX-9397A (HIC Number)
Noridian Healthcare Solutions (Contractor)	1-5903036090 (ALJ Appeal Number

On October 11, 2017, the Medicare Appeals Council (Council) issued a decision in this case. In that decision, the Council concluded that Medicare will not cover the disposable sensors (HCPCS code A9276) furnished to the appellant-beneficiary on August 18, 2016, for use with a continuous glucose monitor (CGM) system. We found that a CGM system does not fall within the durable medical equipment (DME) benefit category; therefore, the sensors furnished to the beneficiary, as supplies for a non-covered item, are non-covered. We further held the appellant financially responsible for the non-covered items.

Now before the Council, the appellant's representative submits a request to reopen the Council's decision. By letter dated November 1, 2017, the appellant's representative explains that her request to reopen is based on a District Court decision, and the recently issued Medicare supplier manual. The appellant has attached copies of the District Court decision, and a section of the Medicare supplier manual, and asserts that the supplier manual distinguishes precautionary medical equipment from a CGM. The Council enters the appellant's request to reopen into the administrative record as Exhibit (Exh.) MAC-2, and the

appellant's request for an extension of time to file a civil action as Exh. MAC-3.

The Council may reconsider an appeal, but only if there is good cause to reopen the case. *See* 42 C.F.R. § 405.980. Good cause may be established when: (1) there is new and material evidence, now available or known, that may result in a different conclusion; or (2) an obvious error was made at the time of the Council's decision or determination. *Id.* § 405.986. As set forth below, we do not find good cause to reopen our prior decision and deny the request for reopening.

DISCUSSION

In the request for reopening, the appellant attached a District Court case issued on October 26, 2017, as a basis for the assertion that the Council's decision in this case was based on an error of law material to the outcome of this case. Exh. MAC-2. We first note that this District Court decision was issued fifteen days after our decision, and thus it was not available or known at the time of our decision. In that District Court case, the court appears to have substituted an interpretation of the phrase "primarily and customarily used to serve a medical purpose" as merely meaning that a device does not have an obvious purpose that is unrelated to health. *See Whitcomb v. Hargan*, Civ. No. 17-CV-14, slip. op. at 11 (October 26, 2017) (DME definition is "clear on its face" in that a "device's primary and customary purpose must be medical as opposed to non-medical."). We disagree with that interpretation. If this requirement merely meant that DME devices must have health-related uses, there would be no point to the further regulatory requirement that a device "generally is not useful to an individual in the absence of an illness or injury." 42 C.F.R. § 414.202. Regulatory language should be read in a manner that gives meaning and effect to all its terms. We conclude that CMS reasonably and within its authority interpreted the regulatory definition of DME to mean that CGM devices must essentially serve or add to therapeutic measures rather than merely be of some medical or health-related use.

Moreover, CMS has expressed a consistent interpretation of the definition of DME as limited to those CGM devices which are suitable for direct determination of treatment actions. That interpretation was embodied in the policy articles explaining that such CGMs (the only ones available at the time of issuance and the kind the appellant used during the dates of service)

were not DME because they were "precautionary." While "precautionary" may be a less than felicitous term in this context, the meaning is not unreasonable. Oxygen units, like glucose monitors, are unlikely to be used in the absence of disease. Preset portable oxygen units may provide additional mobility and convenience which may, in some instances, be very important to a patient, but they do not add any treatment modality or function because they cannot be adjusted to respond to treatment needs. CGM systems like the one the appellant was using may provide information, including alerts, about blood sugar fluctuations, but they similarly do not add any treatment modality or function so long as the patient is required to return to blood glucose measures to make treatment decisions. Where an individual must still use another device to accomplish the medical purpose at issue (i.e., measuring the glucose in the individual's blood), the device is essentially used as an additional precaution, but not for the primary medical purpose.

With regard to the appellant's assertion that the recently issued Medicare supplier manual distinguishes precautionary medical equipment from a CGM, the appellant submitted a section of a supplier manual pertaining to backup equipment with no further explanation. Exh. MAC-2. Upon our careful review, we do not read any language in that supplier manual section that "distinguishes precautionary medical equipment from a CGM" as the appellant asserts. The manual states:

> Backup medical equipment is defined as an identical or similar device that is used to meet the same medical need for the beneficiary but is provided for precautionary reasons to deal with an emergency in which the primary piece of equipment malfunctions.

DME MAC Jurisdiction C Supplier Manual, Ch. 3 at 34 (Fall 2017). First, we note that the excerpt on which the appellant relies is not new and material evidence that was unavailable at the time the Council rendered its decision because the substance of the provision was available in previous versions of the manual, including, for example, the Spring 2017 update. *See* DME MAC Jurisdiction C Supplier Manual, Ch. 3 at 35 (Spring 2017). Moreover, to the extent that the appellant believes that this manual section limits the definition of "precautionary" to backup medical equipment used in emergency situations, we disagree as there is simply no support, and the appellant offers none, for that proposition. Instead, the supplier manual emphasizes the need to distinguish backup equipment from

multiple medically necessary items. However, the CGM was not denied as not medically necessary but instead on the basis that the CGM did not meet the definition of DME. Before any question can arise of whether an item of DME may be reasonable and necessary for medical treatment under particular conditions, a particular device must meet the definition of DME. As indicated in or prior decision, the CGM does not meet the definition of DME.

In sum, we do not find good cause for reopening our decision that Medicare will not cover the CGM sensors provided to the appellant on August 18, 2016. Accordingly, the Council denies the request for reopening.

Due to the high volume of cases that we handle, the Council will not be able to entertain or respond to further requests to reopen or reconsider this case. The Council's October 11, 2017, decision stands as the final decision of the Secretary of Health and Human Services.

Further, in response to the appellant's request, the Council grants the appellant a sixty-day extension of time to file a civil action in federal district court from the date of receipt of this denial of request to reopen. *See* 42 C.F.R. §§ 405.1134 and 405.1136. The date of receipt shall be presumed to be five days from the date of this denial of request to reopen, unless a reasonable showing is made to the contrary. Please include a copy of this denial of request to reopen with your civil complaint. No further extensions of time will be granted.

MEDICARE APPEALS COUNCIL

Debbie K. Nobleman
Administrative Appeals Judge

Date: MAY 18 2018